

REMARKS/ARGUMENTS

In an Office Action dated July 29, 2003, claims 15-24 were rejected. Claims 25 and 26 have been withdrawn from consideration. By this amendment, claims 15, 17, and 18 have been amended. Claims 15-24 remain pending.

Claim Objection

The Examiner has objected to claim 15 as informal. The claim has been amended as suggested by the Examiner. Applicants respectfully request withdrawal of the objection.

Claim Rejections – 35 U.S.C. § 112, Second Paragraph

The Examiner has rejected claims 17, 18, 20, 21, 23, and 24 as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Claim 17 has been amended to depend from claim 16 as suggested by the Examiner. Applicants respectfully request the withdrawal of the rejection of claims 17, 20, and 23.

The Examiner has stated that the recitation “substantially” in claim 18 is indefinite because the term has no particular art-recognized meaning and has not been adequately defined in the specification.

Applicants respectfully disagree with the Examiner’s grounds for rejection and the above statements. One of skill in the art is well versed in performing assays that may determine adhesion of *H. pylori* to epithelial cells and therefore would have no difficulty in recognizing a “substantial” reduction in adhesion. However, in order to facilitate prosecution in this case applicants have amended claim 18, without prejudice or disclaimer, to remove the recitation “substantially”. Applicants therefore respectfully request withdrawal of the rejection of claims 18, 21, and 24.

Claim Rejections – 35 U.S.C. § 102(b)

The Examiner has rejected claim 15 under 35 U.S.C. § 102(b) as being anticipated by Eklind *et al.* (WO 95/00527). The Examiner has alleged that Eklind *et al.* teach that several fucosylated N-acetyl lactosamine carbohydrate structures may be used to treat diseases in humans caused by *H. pylori* infection of human gastric mucosa.

Applicants respectfully disagree with the Examiner's grounds for rejection and the above statements. However, in order to facilitate prosecution in this case applicants have amended the pending claim, without prejudice or disclaimer, to add the recitation "sialylated". In order to anticipate, a reference must teach every element of a claim. Eklind *et al.* fail to teach a "fucosylated sialylated N-acetyl lactosamine carbohydrate structure", so the reference does not anticipate the claimed invention. Applicants therefore respectfully request withdrawal of the rejection of claim 15.

Claim Rejections – 35 U.S.C. § 103(a)

The Examiner has rejected claims 15-24 under 35 U.S.C. § 103(a) as being obvious in light of Schmidt *et al.* (U.S. Patent No. 6,413,936). The Examiner has asserted that Schmidt *et al.* teach glycomimetics of sialyl Lewis x and sialyl Lewis a, which may be used to treat *Helicobacter pylori*. The Examiner has noted that Schmidt *et al.* do not disclose administration of sialyl Lewis x or sialyl Lewis a for treatment of *Helicobacter pylori*. However, the Examiner asserts that it would have been obvious at the time to administer sialyl Lewis x or sialyl Lewis a for treatment of *Helicobacter pylori* infections. The Examiner also asserts that one of ordinary skill in the art would have a reasonable expectation for success.

Applicants respectfully disagree with the Examiner's grounds for rejection and the above assertions. In order to establish a *prima facie* case for obviousness, the cited reference or references must teach or suggest all claim limitations. The Examiner has failed to establish a *prima facie* case because there is no suggestion or motivation to modify the references as suggested by the Examiner, the cited reference itself teaches against the proposed modification, and one of ordinary skill in the art would have no reasonable expectation of success.

First, one of skill in the art would not be motivated to modify Schmidt *et al.* to use sialyl Lewis x or sialyl Lewis a for the treatment of *Helicobacter pylori*. A suggestion or motivation to modify a reference must suggest the **desirability** of the claimed invention. See MPEP 2143.01. The Examiner has merely stated that one of ordinary skill in the art would be motivated to use sialyl Lewis x or sialyl Lewis a because they represent substructures of the naturally occurring selectin ligands and thus would have been effective in controlling the cellular adhesion process underlying the *H. pylori* infection. However, Schmidt *et al.* do not teach or suggest the desirability using of sialyl Lewis x or sialyl Lewis a for any treatment, do not teach or suggest the desirability of using sialyl Lewis x or sialyl Lewis a for treatment of *H. pylori* infection, and do not teach or suggest that *H. pylori* adhesion is mediated through the sialyl Lewis x or sialyl Lewis a portion of selectin ligands. In fact, in column 1, line 64 to column 2, line 8 of Schmidt *et al.* indicates that sialyl Lewis x and sialyl Lewis a are only substructures of selectins and since the affinity and specificity of ligands that bind selectins is unknown, the mimetics are only a promising *starting point* for the disclosed therapeutic anti-inflammatory activity. If the mimetics are only promising starting points for anti-inflammatory activity, this hardly suggests the **desirability** of using sialyl Lewis x or sialyl Lewis a to treat *H. pylori* infection.

Second, Schmidt *et al.* actually teach against the modification suggested by the Examiner. As noted by the Examiner, Schmidt *et al.* indication that, “Due to the structural complexity of SLeX and SLeA, the use of simpler, structurally modified mimetics as antagonists for modulating or suppressing excessive leukocyte adhesion is a promising therapeutic starting point for a strategy for alleviating or healing the above-mentioned disorders.” Schmidt *et al.* teach that the disclosed mimetics are superior to SLeX and SLeA. Specifically, Schmidt *et al.* teach that the mimetics should be used instead of sialyl Lewis x or sialyl Lewis a due to the low molecular weight, significantly enhanced affinity and simpler synthesis of the mimetics. See Column 5, lines 29-35 of Schmidt *et al.* Thus, one of skill in the art would be motivated to *not* use sialyl Lewis x or sialyl Lewis a due to the higher molecular weight, lower affinity and more complicated synthesis. Furthermore, as stated in the MPEP 2143.02, “the proposed modification cannot render the prior art unsatisfactory for its intended purpose.” The intended purpose of the Schmidt *et al.* patent is to provide simpler mimetic compounds to be used instead of sialyl Lewis x or sialyl Lewis a. The

Examiner's proposed modification is contrary to the whole object of the Schmidt *et al.* invention and therefore there is no suggestion or motivation for the modification.

Finally, one of ordinary skill in the art would not have a reasonable expectation for success. As mentioned above, Schmidt *et al.* teach that the sialyl Lewis x or sialyl Lewis a carbohydrate structures are of substantially more complex selectin ligands. According to Schmidt *et al.*, the selectivity of endogenous and other potential ligands for selectins is unknown. See Column 1, line 64 to Column 2 line 8. Thus, one of skill in the art would not know whether *H. pylori* adhesion was mediated by the sialyl Lewis x or sialyl Lewis a portion of the selectin ligand or other portions not represented by the sialyl Lewis x or sialyl Lewis a portion. Due to this uncertainty, one of ordinary skill in the art would not have a reasonable expectation of success. As stated by Schmidt *et al.*, the mimetics only represent "a promising therapeutic starting point". It is worth noting that the Mahdavi *et al.* reference published after the submission of the present application (submitted herewith in a Supplemental IDS) demonstrates that *H. pylori* are capable of binding to sialyl Lewis x.

The Examiner has not established a *prima facie* case of obviousness because there is no motivation to modify Schmidt *et al.* As the Examiner has noted, without such modification, Schmidt *et al.* fail to teach or suggest all of the claim limitations of the present invention and therefore does not render the claimed invention obvious. For the above reasons, the Applicants respectfully request that the Examiner withdraw the obviousness rejection.

CONCLUSION

In light of the above, applicants submit that the pending claims are in condition for allowance. Should there be any remaining issues that remain unresolved; the Examiner is encouraged to contact the undersigned by telephone.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 514862000100. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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